K130580

FEB 2 5 2014

510(k) Summary

Date: February 10, 2014

Owner's Name:
DMG USA, Inc.
23 Frank Mossberg Drive
Attleboro, MA 02703
(508) 226-5660
Registration # not yet assigned
Owner/Operator No. 9005969

Contact Person:
Pamela Papineau, RAC
Delphi Medical Device Consulting, Inc.
5 Whitcomb Avenue
Ayer, MA 01432
(978) 772-3552

Subject Device:
Trade Name: Retraction Paste
Common Name: Retraction Cord
Classification Name: Unclassified, Product Code MVL

Predicate Device:
Trade Name: Expa-Syl - K050180 (Sybron Dental Specialists)
Common Name: Retraction Cord
Classification Name: Unclassified, Product Code MVL

Product Description &
The Retraction Paste is a medium viscosity substance that contains aluminium chloride hexahydrate in a water-based kaolin (clay) inert carrier. The kaolin/water paste provides physical displacement of the gingiva as the material is placed into the sulcus via a manual dispensing syringe. The aluminium chloride hexahydrate component has hygroscopic and astringent properties, which produce a hemostatic/drying effect, and assist in temporarily shrinking the gingival tissue and holding it slightly away (retracted) from the tooth surface, thereby allowing complete access of the impression material.

Indications for Use:
For use for the temporary retraction and hemostasis of the gingival margin during dental procedures such as, but not limited to, dental impressions, seating of temporary and permanent restorations, restorations of cavities and placement of a rubber dam.

Substantial Equivalence:

	DMG USA Retraction Paste (current submission)	Expa-syl (K050180; predicate device)
510(k) Sponsor	DMG USA	Sybron Dental Specialties, Inc.
Indications for Use	For the temporary retraction and hemostasis of the gingival margin during dental procedures such as, but not limited to, dental impressions, seating of temporary and permanent restorations, restorations of cavities and placement of a rubber dam.	For the temporary retraction and hemostasis of the gingival margin during dental procedures such as, but not limited to, dental impressions, seating of temporary and permanent restorations, restorations of cavities and placement of a rubber dam.
Physical Properties	pH, viscosity	pH, viscosity
Chemical Composition	Aluminum chloride hexahydrate in a water-based kaolin paste	Aluminum chloride hexahydrate in a water-based kaolin paste
Operating Principle	Kaolin-based paste physically displaces gingival tissue; aluminum chloride hexahydrate provides gingival tissue retraction, hemostasis and drying of other fluids. Resulting gingival sulcus exposes margin.	Kaolin-based paste physically displaces gingival tissue; aluminum chloride hexahydrate provides gingival tissue retraction, hemostasis and drying of other fluids. Resulting gingival sulcus exposes margin.
How Supplied	Pre-filled cartridge used with dispensing gun; product applied through disposable syringe tips attached to cartridge.	Pre-filled cartridge used with dispensing gun; product applied through disposable syringe tips attached to cartridge.

Conclusion:

Substantial Equivalence for the DMG USA Retraction Paste is based upon comparison to the physical properties, chemical composition, operating principle, product packaging / delivery mechanism and indications for use of the predicate device. Technological characteristics and non-clinical performance data provided in this 510(k) consist of chemical composition, description of product packaging/delivery mechanism, and physical properties measurements (pH and viscosity). The Retraction Paste is identical to the predicate device in terms of these technological characteristics and non-clinical performance data; therefore, the Retraction Paste has been shown to be substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

February 25, 2014

DGM USA, Incorporated
C/O Ms. Pamela Papineau, RAC
Delphi Medical Device Consulting, Incorporated
5 Whitcomb Avenue
Ayer, MA 01432

Re: K130580
Trade/Device Name: Retraction Paste
Regulation Name: None
Regulatory Class: Unclassified
Product Code: MVL
Dated: December 30, 2013
Received: January 17, 2014

Dear Ms. Papineau:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Erin I. Keith, M.S.
Acting Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): 130580

Device Name: **Retraction Paste**

Indications for Use:

For the temporary retraction and hemostasis of the gingival margin during dental procedures such as, but not limited to, dental impressions, seating of temporary and permanent restorations, restorations of cavities and placement of a rubber dam.

Prescription Use X OR Over-the -Counter Use ____

(Per 21 CFR 801 Subpart D) (Per 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Mary S. Runner -S
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